REMARKS

The Official Action dated June 2, 2004 has been carefully considered. It is believed that the changes presented herein, taken with the following remarks, are sufficient to place this application in condition for allowance. Accordingly, reconsideration is respectfully requested.

By the present amendment, claim 22 is amended to recite the method of treating glaucoma or ocular hypertension in a subject's eye is for a period of at least six months, as set forth at page 5 of the present application. As this amendment does not involve any introduction of new matter, entry is believed to be in order and is respectfully requested.

In the Official Action, claim 4 was rejected under 35 U.S.C. §102(b) as being anticipated by Chemical Abstract 87:63008. The Examiner asserted that the chemical abstract teaches use of the claimed prostaglandin in a pharmaceutical formulation as a bronchodilator.

However, Applicants submit that the composition of claim 4 is not anticipated by and is patentably distinguishable from the teachings of the cited chemical abstract. Accordingly, this rejection is traversed and reconsideration is respectfully requested.

More particularly, the cited chemical abstract discloses the synthesis and bronchodilator activity of DL-16,16-trimethylene prostaglandins. On the other hand, claim 4 is directed to a composition for the treatment of glaucoma and ocular hypertension. The composition comprises a therapeutically active and physiologically acceptable amount of 15(R,S)-16,16-trimethylene PGE_2, or an alkyl ester thereof, or a pharmaceutically acceptable salt thereof, and an ophthalmologically-compatible vehicle. Additionally, the composition is adapted for topical application to the eye. Applicants find no teaching or suggestion in the cited chemical abstract relating to a composition containing a prostaglandin in combination with an ophthalmologically-compatible vehicle, or relating to a composition adapted for topical application to the eye.

Anticipation under 35 U.S.C. §102 requires that each and every element as set forth in the claims is found, either expressly or inherently described, in a single prior art reference, *In re Robertson*, 49 U.S.P.Q.2d 1949, 1950 (Fed Cir. 1999). In view of the failure of the cited chemical abstract to teach the combination of a prostaglandin as presently claimed and an ophthalmologically-compatible vehicle, and the failure of the cited chemical abstract to teach a composition adapted for topical application to the eye, the cited chemical abstract fails to disclose each and every element set forth in claim 4. Thus, the chemical abstract does not anticipate claim 4 under 35 U.S.C. §102.

The Examiner has asserted that Applicants have alleged criticality to the different use of the claimed composition, rather than a difference in the composition. However, the composition defined by claim 4 comprises not only the recited PGE_2 compound, but also an ophthalmologically-compatible vehicle. Additionally, the composition is adapted for topical application to the eye. In contrast, the cited chemical abstract provides no teaching relating to an ophthalmologically-compatible vehicle, or a composition adapted for topical application to the eye. One skilled in the art will recognize that the disclosure of a particular compound does not inherently disclose a composition adapted for topical application to the eye, or the compound in combination with an ophthalmologically-compatible vehicle. Thus, Applicants are not relying on an intended use of the composition of claim 4 to distinguish over the cited chemical abstract, but rather on the components and properties of the claimed composition. It is therefore submitted that the composition of claim 4 is not anticipated by the cited chemical abstract under 35 U.S.C. §102, whereby the rejection has been overcome. Reconsideration is respectfully requested.

Claims 5, 7-11 and 18-23 were rejected under 35 U.S.C. §102(b) as being anticipated by the Stjernschantz et al U.S. Patent No. 5,296,504. The Examiner asserted that Stjernschantz et al teach the use of the claimed prostaglandins in a pharmaceutical formulation for the treatment of glaucoma.

However, Applicants submit that the composition defined by claim 5 and the methods defined by claims 77-11 and 18-23 are not anticipated by and are patentably distinguishable from the teachings of Stjernschantz et al. Accordingly, this rejection is traversed and reconsideration is respectfully requested.

More particularly, claim 5 is directed to a composition for the treatment of glaucoma and ocular hypertension. The composition comprises a therapeutically effective and physiologically acceptable amount of a prostaglandin analog which is a selective agonist for EP_1 prostanoid receptors, or a pharmaceutically acceptable salt or ester thereof, and an ophthalmologically-compatible vehicle. The prostaglandin analog is 13,14-dihydro-17-(3-fluorophenyl)-18,19,20-trinor-PGE_2 or an alkyl ester thereof. The composition is adapted for topical application to the eye. As noted in the present specification, Applicants have discovered that the compound of claim 5 is an EP_1 selective agonist and therefore is advantageous for reducing intraocular pressure with significantly reduced melanogenesis as a side effect (see, for example, the specification at page 5, second and third paragraphs).

Stjernschantz et al disclose prostaglandin derivatives for the treatment of glaucoma or ocular hypertension. Derivatives of PGA, PGB, PGD, PGE and PGF, in which the omega chain contains a ring structure, are disclosed. Numerous compounds are covered by the generic formula which Stjernschantz et al disclose. However, Applicants find no specific teaching by Stjernschantz et al relating to the prostaglandin analogue included in the composition of claim 5, namely 13,14-dihydro-17-(3-fluorophenyl)-18,19,20-trinor-PGE_2 or an alkyl ester thereof. Additionally, Applicants find no teaching by Stjernschantz et al relating to prostaglandin analogues which are selective agonists for EP_1 prostanoid receptors. In fact, Applicants advise that compounds similar to that of claim 5, for example 13,14-dihydro-17-phenyl-18,19,20-trinor-PGF_2 alpha (omitting the 3-fluoro substituent on the phenyl group), which is the free acid of latanoprost, the active ingredient of Xalatan is a prostaglan FP receptor agonist (see, for example, the previously submitted Stjernschantz et al, *Drugs of the Future*, 17(8):691-704 (1992), particularly page 699), as is 16-phenoxy(3-trifluoromethyl)-17,18,19,20-tetranor-PGF_2 alpha (having a fluoro group but in combination with other different substituents), which is the free acid of travapost, the active ingredient of Travatan.

Thus, not only is the prostaglandin analogue in the composition of claim 5 not specifically disclosed by Stjernschantz et al, Applicants have discovered that it exhibits a selective agonist property different from similar compounds specifically disclosed by Stjernschantz et al. In view of the failure of Stjernschantz et al to specifically teach the prostaglandin analog included in the composition of claim 5, and to recognize the selective agonist for EP_1 prostanoid receptor activity exhibited thereby, Stjernschantz et al do not disclose each and every element of claim 5. Thus, Stjernschantz et al do not anticipate claim 5 under 35 U.S.C. §102, *In re Robinson, supra*. It is therefore submitted that the rejection of claim 5 has been overcome. Reconsideration is respectfully requested.

Finally, claims 7-11 and 18-23 are directed to methods of treating glaucoma or ocular hypertension in a subject's eye for a period of at least six months, while reducing melanogenesis. According to independent claim 22, the method comprises contacting the surface of the eye with an effective intraocular pressure reducing amount of a therapeutically active and physiologically acceptable prostaglandin analog which is a selective agonist for EP_1 prostanoid receptors, or a pharmaceutically acceptable salt or ester thereof, any melanogenesis which is caused by the method of treatment being reduced as compared with that obtained by a method of treatment in which a prostaglandin analog which is not a selective agonist for EP_1 prostanoid receptors is employed. Thus,

the present methods provide improvement over chronic treatment methods, i.e., those lasting greater than six months, employing a prostaglandin or analog which is not a selective agonist for EP_1 prostanoid receptors.

As noted above, numerous prostaglandin compounds are covered by the generic formula which Stjernschantz et al disclose. However, Applicants find no specific teaching by Stjernschantz et al relating to prostaglandin analogues which are selective agonists for EP_1 prostanoid receptors, or relating to any improvement obtained by use of such compounds in a chronic treatment method as presently claimed. In fact, as noted above, commercially available prostaglandins such as 13,14-dihydro-17-phenyl-18,19,20-trinor-PGF_2 alpha, which is the free acid of latanoprost, the active ingredient of Xalatan, and 16-phenoxy(3-trifluoromethyl)-17,18,19,20-tetranor-PGF_2 alpha, which is the free acid of travapost, the active ingredient of Travatan, are prostaglan FP receptor agonists, rather than selective agonists for EP_1 prostanoid receptors.

Further, Applicants find no teaching by Stjernschantz et al relating to a method of treating glaucoma or ocular hypertension in a subject's eye for a period of at least six months, while reducing melanogenesis. Particularly, Stjernschantz et al provide no teaching that melanogenesis can be reduced or avoided in such a chronic treatment method by administering a prostaglandin analog which is a selective agonist for EP_1 prostanoid receptors. Thus, Stjernschantz et al do not anticipate claim 22, or claims 7-11, 18-21 and 23 dependent thereon, under 35 U.S.C. §102, *In re Robinson, supra*. It is therefore submitted that the rejection of claims 7-11 and 18-23 has been overcome. Reconsideration is respectfully requested.

It is believed that the above represents a complete response to the rejections under 35 U.S.C. §102 and places the present application in condition for allowance. Reconsideration and an early allowance are requested.

CONCLUSION

In light of the foregoing amendment and remarks, Applicant respectfully submits that this application is now in condition for proper examination. Applicant invites the Examiner to telephone the undersigned attorney if there are any issues outstanding that have not been addressed to the Examiner's satisfaction.

Applicant petitions for a one-month extension ($110.00) of the due date for responding to the Office Action dated June 2, 2003. An Amendment and Response To The Office Action is submitted herewith. Applicant includes 1 new dependent claim, for which no additional fee is incurred.

Please charge the total amount of $110.00 covering the extension fee to our Deposit Account No. 500329. A copy of this paper is enclosed.

If the enclosed payment is insufficient or if any other fee is required, please charge all necessary fees to Deposit Account No. 500329.

Respectfully submitted,

Date: October 4, 2004

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